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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,782	10/01/2003	Simon J. Mantell	PC10921B	8379

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PFIZER INC.
PATENT DEPARTMENT, MS8260-1611
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GROTON, CT 06340

EXAMINER	
KHARE, DEVESH	
ART UNIT	**PAPER NUMBER**
1623	

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/676,782	MANTELL ET AL.	
	Examiner	Art Unit	
	Devesh Khare	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *58 and 61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *58 and 61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/25/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 1-57, 59,60 and 62-77 have been cancelled by the Preliminary Amendment dated 10/01/2003.
Claims 58 and 61 are currently pending.

An action on the merits of claims 58 and 61 is contained herein below.

35 U.S.C. 112, first paragraph rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 58 and 61 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention of record. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 58 and 61, are directed to a method of treating an inflammatory disease and diseases such as septic shock, male erectile dysfunction, male factor infertility, female factor infertility, hypertension, stroke, epilepsy, cerebral ischaemia, peripheral vascular disease, post-ischaemic reperfusion injury and other diseases listed in claim 61 in a mammal with an effective amount of adenosine derivative having the Formula I. The support in the specification is not adequate for the claim to use the compounds of formula (I) for a method of treating an inflammatory disease and diseases such as septic shock, male

erectile dysfunction, male factor infertility, female factor infertility, hypertension, stroke, epilepsy, cerebral ischaemia, peripheral vascular disease, post-ischaemic reperfusion injury and other diseases listed in claim 61 in a mammal. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

The factors regarding undue experimentation have been summarized in *In re Wands,* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Circ. 1988) as follows:

(1) The quantity of experimentation necessary (time and expense);

(2) The amount of direction or guidance presented;

(3) The presence or absence of working examples of the invention;

(4) The nature of the invention;

(5) The state of the prior art;

(6) The predictability or unpredictability of the art;

(7) The breadth of the claims; and

(8) The relative skill of those in the art.

1. QUANTITY OF EXPERIMENTATION

With regard to factor one the quantity of experimentation needed, a method of treating an inflammatory disease and diseases such as septic shock, male erectile dysfunction, male factor infertility, female factor infertility, hypertension, stroke, epilepsy, cerebral ischaemia, peripheral vascular disease, post-ischaemic reperfusion injury and other diseases listed in claim 61 in a mammal with an effective amount of adenosine derivative having the Formula I. At the very least, experimentation correlative to establishing a method for treating a mammal having an inflammatory disease which is within scope of treating a mammal having an inflammatory disease. The absence of specific disclosures or the correlation of data to support applicant's assertions, invites the skilled artisan to engage in undue experimentation, to treat a subject having an inflammatory disease.

2. GUIDANCE PROVIDED

There is little guidance given in the specification as to the specific use of an effective amount of adenosine derivative having the Formula I in a method for treating a mammal having an inflammatory disease. This lack of guidance would indeed impose the burden of undue experimentation in determining the degree, if any, for the elimination of human health conditions set forth. There is not seen any guidance in the specification drawn to establishing a correlation between the use of an effective amount of adenosine derivative having the Formula I and a method for treating a mammal having an inflammatory disease. No guidance is provided to use adenosine derivative having the Formula I in a method for treating a mammal having an inflammatory disease.

3. WORKING EXAMPLES IN SPECIFICATION

The EXAMPLES advanced in the instant specification are not seen as sufficient to support the breadth of the claims for treating a mammal having an inflammatory disease. It is noted that Examples 1-35 and Preparations 1-74 provide the synthesis of said compounds. The pharmacological data provided on page 161 is not sufficient.

4. NATURE OF THE INVENTION

It is known in this art that certain adenosine derivatives have efficacy in treating specific conditions having an inflammatory disease. The exact mechanism of action and the effects of adenosine derivatives is disclosed (see abstract) (Olsson et al.; J. Of Medicinal Chem. 1986, 29(9), pages 1683-1689; see IDS).

5. STATE OF THE PRIOR ART

The instant claims are drawn to use an effective amount of adenosine derivative having the Formula I in a method for treating a mammal having an inflammatory disease. The following reference is cited to show the state of the prior art:

Olsson et al.; J. Of Medicinal Chem. 1986, 29(9), pages 1683-1689; see IDS.

6. THE PREDICTABILITY OF THE ART

To extrapolate the data presented in the disclosure for the class of compounds of claim 58 and 61 (adenosine derivatives), for the treatment of a mammal having an inflammatory disease not seen to be enabled or taught in the prior art. Neither the specification nor the prior art provides adequate guidance for equivocating the treatment data for the compounds of claim 58 and 61, for the treatment of a mammal having an inflammatory disease.

7. BREATH OF THE CLAIMS

Claims 58 and 61, wherein an effective amount of adenosine derivative having the Formula I, are directed to a method for treating a mammal having an inflammatory disease. Dependent claim limitations include the diseases such as septic shock, male erectile dysfunction, male factor infertility, female factor infertility, hypertension, stroke, epilepsy, cerebral ischaemia, peripheral vascular disease, post-ischaemic reperfusion injury and other diseases listed in claim 61.

8. THE RELATIVE SKILL IN THE ART

The relative skill in the art as it relates to a method for treating a mammal having an inflammatory disease with an effective amount of adenosine derivative having the Formula I, is that of a Ph.D. or M.D. level.

Presently, the instant specification is not seen to provide an enabling disclosure for the scope of the invention as set forth in claims, which encompass for treating a mammal having an inflammatory disease with the compound of claims 58 and 61. It is noted that Law requires that the disclosure of an application shall inform those skilled in the art how to use applicant's alleged discovery, not how to find out how to use it for themselves, see In re Gardner et al. 166 USPQ 138 (CCPA 1970). In the instant case, the amount of experimentation needed to verify the efficacy of the said compound of formula presented in claims 58 and 61 for treating a mammal having an inflammatory disease would indeed be voluminous and unduly burdensome in view of the teachings of the instant disclosure.

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 58 and 61 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 46,47 and 53 of U.S. Patent No. 6,753,322 ('322) and claims 8,9 and 11 of U.S. Patent 6,525,032 ('032).

Although the conflicting claims are not identical, they are not patentably distinct from each other because both the '322 and '032 patents disclose a method of treating a respiratory disease and agonizing the A2a receptor in a mammal by administering to said mammal with an effective amount of an adenosine derivative having the structure I of claim 1 wherein said method is encompassed by or has substantial overlap with the method of the instant claims. However, the instant method is for a method of treating an inflammatory disease and diseases such as septic shock, male erectile dysfunction, male factor infertility, female factor infertility, hypertension, stroke, epilepsy, cerebral

ischaemia, peripheral vascular disease, post-ischaemic reperfusion injury and other diseases listed in claim 61 in a mammal with an effective amount of adenosine derivative having the Formula I which is the underlying mechanism of agonizing the A2a receptor by which the methods of the issued claims are accomplished.

The examiner notes the instant claims and the '322 and '032 patents claims do indeed substantially overlap and this obviousness-type double patenting rejection is necessary to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees.

Any inquiry concerning this communication or earlier communications from the

Examiner should be directed to Devesh Khare whose telephone number is 571-272-0653. The examiner can normally be reached on Monday to Friday from 8:00 to 4:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, Supervisory Patent Examiner, Art Unit 1623 can be reached at 571-272-0661. The official fax phone numbers for the organization where this application or proceeding is assigned is (703) 308-4556 or 308-4242.
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Devesh Khare, Ph.D.,J.D.
Art Unit 1623
January 13,2004

JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
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